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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/535,390	03/24/00	GHOSH B	U 012673-3

000140
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HM12/0927

EXAMINER	
KWON, B	
ART UNIT	PAPER NUMBER
1614	8

DATE MAILED: 09/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/535,390	GHOSH ET AL.	
	Examiner	Art Unit	
	Brian-Yong S Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Summary of Action

I. The rejection of claim 2 under 35 USC 112, second paragraph, will be maintained.

II. The rejection of claim 1 under 35 USC 102 (b) as anticipated by Aggarwal (WO 9709877) will be maintained.

III. Claims 2-8 will be rejected under 35 USC 103(a) as being unpatentable over Aggarwal et al. in view of Meisner et al. ("Pyrrodidine Dithiocarbamate Increases survival in mouse endotoxin shock", 24th Central European Congress on Anaesthesiology, 1995).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites a method of treating septic shock condition, but each method steps in claim 2 teach a laboratory diagnostic procedure for confirming the activity of curcumin on LPS induced septic shock by monitoring symptoms and probing the reduction in neutrophil infiltration. It is noted that applicants have clearly failed to further limit the preamble of the claim. Accordingly claims 3-8, which are dependent claims of rejected claim 2, are also rejected, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Aggarwal (WO 9709877).

This rejection is analogous to the original rejection as anticipated by Aggarwal.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aggarwal (WO 9709877) in view of Meisner et al. ("Pyrrodidine Dithiocarbamate Increases survival in mouse endotoxin shock", 24th Central European Congress on Anaesthesiology, 1995).

Aggarwal (WO 9709877) teach a use of curcumin in treating septic shock (by inhibiting the activation of the NF-kB transcription factor), wherein said curcumin is administered in a dose of from about 1mg/kg to about 100mg/kg (see from page 1 line 21 to page 2 line 2 as well as claim 1and 3). However, Aggarwal fails to teach the use of curcumin in treating LPS induced septic shock conditions as well as monitoring the activity of curcumin in treating said conditions by observing septic shock symptoms and probing the reduction in neutrophil infiltration from blood vessels to the underlying tissue.

Meisner et al. ("Pyrrodidine Dithiocarbamate Increases survival in mouse endotoxin shock", 1995, 24th Central European Congress on Anaesthesiology, 1995) discloses the scientific background that the activation of NF-kB transcription factor is implicated in the induction of numerous proinflammatory cytokines in septic shock and endotoxin (LPS)-induced stimulation of macrophages. The reference discloses that "the induction of septic shock in critical ill patients

is thought to be elicited by repeated release of bacterial endotoxin. In animal models septic shock can be induced by i.p. or i.v. injection of high doses of LPS…This overshooting immune stimulation is thought to cause organ damage, circulatory failure and death" (see from pages 1 thru 2).

One having ordinary skill in the art would have expected that curcumin would be useful in treating LPS induced septic shock conditions (by inhibiting the activation of the transcription factor, NF-kB). Although Meisner et al. does not teach the role of neutrophil in the process of LPS induced septic shock condition, the examiner finds that such underlying pharmacological pathway is not critical to the present invention since the teaching of Aggarwal makes clear that curcumin is useful in treating septic shock condition, absent evidence to the contrary.

The prior art does not disclose time interval requirement for the initial and subsequent dose of curcumin which is administered prior to and after the said injection of LPS. However, differences in time interval requirements will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such time periods is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable time periods by routine experimentation.

Response to Arguments

Applicant's arguments filed on July 20, 2001 have been fully considered but they are not persuasive.

Applicant's argument takes position that "Although reference is made in the specification and in the claims of Aggarwal to treating toxic/septic shock, no tests were carried out to study the effects of curcumin on septic shock-even on "normal" cell lines…This is just a supposition that curcumin may be beneficial in treating septic shock. There is no test data to support this statement nor is there any disclosure that would enable one of skill in the art to use curcumin to treat septic shock, which is one of the requirements that must be meet if a reference is properly cited under 35 USC 102(b)". This is spurious argument. It is possible to make a 35 USC 102 rejection even if the reference does not itself teach one of ordinary skill how to practice the invention, i.e., how to make or use the article disclosed. If the reference teaches every claimed element of the article, secondary evidence, such as other patents or publications, can be cited to show public possession of the method of making and/or using. *In re Donohue, 766 F.2d at 533, 226 USPQ at 621.*

In the alternative, even if there is no "enabling disclosure" alleged by the applicant, "it is prior art for all that it teaches." *Beckman Instruments v. LKB Produckter AB, 892 F.2d 1547, 1551, 13 USPQ2d 1301, 1304 (Fed. Cir. 1989).* Therefore, "a non-enabling reference may qualify as prior art for the purpose of determining obviousness under 35 USC 103." *Symbol Technologies Inc. V. Opticon Inc., 935 F.2d 1569, 1578, 19 USPQ2d 1241, 1247 (Fed. Cir. 1991).* Furthermore, the fact that the applicant may have discovered a new pharmacological mechanism for curcumin is not considered patentably distinctive over the prior art which are directed to the same therapeutic application (for the treatment of septic shock condition).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Monday through Friday from 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600